United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued March 17, 2005 Decided April 8, 2005

No. 04-5238

JEROME STEVENS PHARMACEUTICALS, INC.,
APPELLANT

v.

FOOD & DRUG ADMINISTRATION, ET AL.,
APPELLEES

Appeal from the United States District Court
for the District of Columbia
(No. 02cv01939)

Samuel H. Israel argued the cause for appellant. With him on the briefs were *John P. Halfpenny* and *Russell J. Gaspar*.

Thomas M. Bondy, Attorney, U.S. Department of Justice, argued the cause for appellees. With him on the brief were *Peter D. Keisler*, Assistant Attorney General, *Kenneth L. Wainstein*, U.S. Attorney, and *Mark B. Stern*, Attorney.

Before: SENTELLE, HENDERSON and ROGERS, *Circuit Judges*.

Opinion for the Court filed by *Circuit Judge* ROGERS.

ROGERS, *Circuit Judge*: The Food and Drug Administration ("FDA") posted on its website trade secrets and confidential information contained in a New Drug Application ("NDA") filed by Jerome Stevens Pharmaceuticals, Inc. ("JSP") for Unithroid, a levothyroxine sodium ("LS") drug used to treat thyroid diseases. FDA also extended the NDA approval deadline, allowing JSP's competitors to continue marketing their unapproved LS drugs for three years after Unithroid had been approved. JSP filed a six-count complaint against FDA, including two counts under the Federal Tort Claims Act ("FTCA"), 28 U.S.C. §§ 2671-2680 (2000), for misappropriation of trade secrets and breach of a confidential relationship, and one count under the Administrative Procedure Act ("APA"), 5 U.S.C. § 706 (2000), for the arbitrary and capricious extension of the NDA deadline. The district court dismissed the complaint for lack of subject matter jurisdiction under Rule 12(b)(1) of the Federal Rules of Civil Procedure, and JSP appeals the dismissal of Counts I, II, and VI. We conclude that the district court properly dismissed the APA claim in Count VI but erred as a matter of law in ruling that the tort claims in Counts I and II were barred by the discretionary function and intentional tort exceptions to the FTCA. Accordingly, we affirm the dismissal of Count VI, reverse the dismissal of Counts I and II, and remand the case to the district court for further proceedings.

I.

The court reviews the district court's dismissal of the complaint *de novo* and "accept[s] all of the factual allegations in [the] complaint as true." *Sloan v. U.S. Dep't of Housing & Urban Dev.*, 236 F.3d 756, 759 (D.C. Cir. 2001) (second

alteration in original) (quoting *United States v. Gaubert*, 499 U.S. 315, 327 (1991)) (internal quotation marks omitted).

JSP is a small New York company that manufactures Unithroid, an orally administered LS tablet used to treat thyroid diseases. On August 14, 1997, FDA announced that, although doctors had been prescribing LS tablets to millions of patients since the 1950s, they were considered "new drugs" because "no currently marketed orally administered levothyroxine sodium product ha[d] been shown to demonstrate consistent potency and stability." 62 Fed. Reg. 43,535, 43,538 (Aug. 14, 1997). Accordingly, FDA required LS manufacturers to submit NDAs for FDA approval by August 14, 2000, and allowed the continued marketing of unapproved LS tablets until that date. *See id.* FDA stated that after the NDA deadline, any unapproved orally administered LS drug would be "subject to regulatory action." *Id.*

On October 19, 1999, JSP filed an NDA for Unithroid. Pursuant to FDA requirements, the NDA contained JSP's "trade secrets and confidential information for the manufacture of safe, stable, and effective LS," Compl. ¶ 28, including "[t]he order in which Unithroid's ingredients are added together; the steps that the additions go through in the formation of Unithroid's tablets; and the processing of the active ingredient, levothyroxine sodium," *id.* ¶ 19. On April 26, 2000, FDA extended the August 14, 2000 approval deadline by one year to allow manufacturers additional time to conduct studies and to prepare applications. 65 Fed. Reg. 24,488, 24,489 (Apr. 26, 2000).

On August 21, 2000, FDA approved Unithroid, making it the first orally administered LS drug to be approved under the new requirements. The next day, without JSP's knowledge or consent, FDA posted on its website JSP's trade secrets and confidential information for manufacturing Unithroid. On

December 18, 2000, upon discovering FDA's disclosure of its trade secrets, JSP demanded that the information be removed immediately from FDA's website. After repeated requests, FDA removed some of the information on January 12, 2001, and the remaining information on January 23, 2001. Consequently, JSP's trade secrets were available to the public on FDA's website for five months.

Meanwhile, following FDA approval and anticipating increased demand for Unithroid, JSP doubled its staff and invested $2 million in expanding its facilities. On November 17, 2000, JSP filed a petition asking FDA not to extend the NDA deadline a second time, asserting that it was prepared to supply the entire market for LS drugs. Nonetheless, on July 13, 2001, FDA announced that because "it will take time for the millions of patients taking unapproved [LS] products to switch to approved products, and for manufacturers of approved products to scale up their production and to introduce this increased production into the distribution chain," manufacturers with NDAs pending by August 14, 2001, could continue marketing their unapproved LS tablets for an additional two years. 66 Fed. Reg. 36,794, 36,794 (July 13, 2001). Following this announcement, Abbott Laboratories "flooded the retail market" with Synthroid, its unapproved LS tablet. Compl. ¶ 47. "Having lost de facto market exclusivity due to FDA's publication of its secrets and FDA's extensions of compliance deadlines," JSP was forced to lay off half its workforce and to destroy excess Unithroid worth up to $30 million. *Id.* ¶ 48.

On October 2, 2002, JSP filed a six-count complaint against FDA in the district court. Counts I and II alleged that, by disclosing JSP's trade secrets and confidential information, FDA misappropriated JSP's trade secrets and breached its confidential relationship with JSP. Counts III and IV alleged that FDA's disclosure of JSP's trade secrets violated procedural and

substantive due process. Counts V and VI alleged that FDA's disclosure of JSP's trade secrets and its extensions of the NDA deadlines were arbitrary and capricious under the APA. The complaint sought more than $1.3 billion in compensatory damages "for [JSP's] injuries resulting from [FDA's] misappropriation of [JSP's] trade secrets and breach of FDA's confidential relationship with [JSP]," Compl. ¶ 118, and declaratory relief for the remaining claims.

FDA filed a motion to dismiss for lack of subject matter jurisdiction under Rule 12(b)(1), which the district court granted. *See Jerome Stevens Pharm., Inc. v. FDA*, 319 F. Supp. 2d 45, 47 (D.D.C. 2004) ("*JSP*"). The district court construed Counts I and II as alleging injuries caused solely by FDA's extensions of the NDA deadlines, and ruled that the tort claims in those counts were barred by federal sovereign immunity because the deadline extensions fell within both the discretionary function and intentional tort exceptions to the FTCA. *Id.* at 50-52. The district court ruled that Counts III, IV, and V failed to present a live case or controversy because FDA had already removed JSP's trade secrets from its website. *Id.* at 52-54. Finally, the district court ruled that Count VI was barred by the APA's presumption that agency enforcement actions are not subject to judicial review. *Id.* at 54-57. JSP appeals the dismissal of Counts I, II, and VI.

II.

The FTCA "grants federal district courts jurisdiction over claims arising from certain torts committed by federal employees in the scope of their employment, and waives the government's sovereign immunity from such claims." *Sloan*, 236 F.3d at 759; *see* 28 U.S.C. §§ 1346(b), 2674 (2000). The grant of jurisdiction and waiver of sovereign immunity are subject to several exceptions, including the discretionary function exception and the intentional tort exception. *See* 28 U.S.C. § 2680. The

discretionary function exception bars claims "based upon the exercise or performance or the failure to exercise or perform a discretionary function or duty on the part of a federal agency or an employee of the Government, whether or not the discretion involved be abused." *Id.* § 2680(a). The intentional tort exception bars "[a]ny claim arising out of assault, battery, false imprisonment, false arrest, malicious prosecution, abuse of process, libel, slander, misrepresentation, deceit, or interference with contract rights." *Id.* § 2680(h).

To determine whether the discretionary function exception applies, the court must engage in a two-part inquiry. *Gaubert*, 499 U.S. at 322-23; *Macharia v. United States*, 334 F.3d 61, 65 (D.C. Cir. 2003). First, the court must determine whether the challenged action involves "an element of judgment or choice," or whether federal law "specifically prescribes a course of action for an employee to follow," leaving the employee "no rightful option but to adhere to the directive." *Gaubert*, 499 U.S. at 322 (quoting *Berkovitz v. United States*, 486 U.S. 531, 536 (1988)) (internal quotation marks omitted); *Macharia*, 334 F.3d at 65. Second, the court must determine whether the challenged action is "of the kind that the discretionary function exception was designed to shield" — that is, actions "based on considerations of public policy." *Gaubert*, 499 U.S. at 322-23 (quoting *Berkovitz*, 486 U.S. at 536, 537) (internal quotation marks omitted); *Macharia*, 334 F.3d at 65.

JSP's complaint challenges both FDA's disclosure of JSP's trade secrets and FDA's extensions of the NDA deadlines in favor of JSP's competitors. The parties appear to agree that the disclosure of trade secrets is not a discretionary function because federal laws prohibit it. *See* Br. of Appellant at 27 (citing 18 U.S.C. § 1905 (2000); 21 U.S.C. § 331(j) (2000); 5 U.S.C. § 552(b)(4) (2000); 21 C.F.R. § 314.430 (2004)); Br. of Appellee at 18-23. The parties also appear to agree that the extension of

the NDA deadline is a discretionary function because it involves an element of choice and is based on considerations of public health. *See* Br. of Appellant at 31-32; Br. of Appellee at 17-20; Reply Br. of Appellant at 4-10. Thus, the only issue in dispute is whether JSP's tort claims are "based upon" the disclosure of trade secrets or the extensions of the NDA deadlines.

In dismissing Counts I and II for lack of subject matter jurisdiction, the district court interpreted those counts as alleging injuries arising from FDA's extensions of the NDA deadlines rather than from FDA's disclosure of JSP's trade secrets. *See JSP*, 319 F. Supp. 2d at 51. Based on this interpretation, the district court ruled that JSP's tort claims were barred by the discretionary function exception because "extending the deadlines clearly involves 'an element of judgment or choice'" and is based on "public-policy considerations regarding the health needs of the millions of thyroid patients." *Id.* at 52 (quoting *Macharia*, 334 F.3d at 65). The district court also stated in a footnote that "[t]he intentional-torts exception also appears to bar the tort claims, as the claims arguably 'arise out of' [FDA's] alleged interference with the contract rights and prospective economic advantage of [JSP] and its partner, Watson Laboratories." *Id.* at 52 n.9; *see also id.* at 50 (citing 28 U.S.C. § 2680(h); *Art Metal-U.S.A., Inc. v. United States*, 753 F.2d 1151, 1155 (D.C. Cir. 1985)).

The district court based its interpretation of Counts I and II on the economic loss report that JSP submitted as part of its administrative claim for damages. *See JSP*, 319 F. Supp. 2d at 50-51 & n.7. The report explains the basis for JSP's claim for $1.3 billion in compensatory damages, relying on the assumption that JSP and Jones Pharma — the only other LS manufacturer to meet the August 14, 2001 deadline — "would have split 90% of the market between them." *Id.* at 50-51 (quoting Mem. in Support of the United States' Mot. to Dismiss, Attach. 1 at 1).

This outcome was possible, the district court noted, "only if FDA had not extended the August 2001 deadline to allow other LS manufacturers to remain in the market." *Id.* at 51. The district court thus concluded that "the action causing [JSP's] injury was not the disclosure, but rather the deadline extensions (and more specifically, the July 2001 extension)." *Id.* JSP points out, however, that the report was not submitted as part of the complaint but was instead attached to FDA's motion to dismiss. Although the complaint sought the same amount of damages as the amount analyzed in the economic loss report, JSP maintains that it is not barred from relying on "other expert reports or damages evidence at trial to prove the claims in Counts I and II." Br. of Appellant at 32 n.8. For the following reasons, we hold that the district court erred as a matter of law in concluding that the complaint failed to allege an independent injury caused by FDA's disclosure of JSP's trade secrets.

A.

At the pleading stage, the issue before the district court was not whether JSP had established sufficient proof of damages caused by FDA's disclosure of JSP's trade secrets, but whether JSP had sufficiently pled claims for such damages. *Cf. Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974). While the district court may consider materials outside the pleadings in deciding whether to grant a motion to dismiss for lack of jurisdiction, *see Herbert v. Nat'l Acad. of Sciences*, 974 F.2d 192, 197 (D.C. Cir. 1992), the court must still "accept all of the factual allegations in [the] complaint as true," *Gaubert*, 499 U.S. at 327 (quoting *Berkovitz*, 486 U.S. at 540) (internal quotation marks omitted). Count I of the complaint alleged that JSP's NDA for Unithroid contained trade secrets and confidential information; that FDA disclosed such information on its website; and that "FDA's disclosure of [JSP's] trade secrets and confidences has caused [JSP] substantial and irreparable injury." Compl. ¶ 75. Count II alleged that FDA had a legal duty to maintain the confidentiality

of proprietary information contained in JSP's NDA; that FDA breached that duty by posting JSP's information on its website; and that "FDA's disclosure of [JSP's] confidential information for Unithroid has caused [JSP] to lose protection for its property interest in the confidences unlawfully disclosed and has thus caused [JSP] to suffer substantial and irreparable injury." Compl. ¶ 85. These allegations sufficiently pled claims for damages caused by FDA's disclosure of JSP's trade secrets and confidential information.

In treating Counts I and II as claims arising from FDA's extensions of the NDA deadlines, the district court relied on JSP's statement that it "lost de facto market exclusivity due to FDA's publication of its secrets *and* FDA's extension of compliance deadlines." *JSP*, 319 F. Supp. 2d at 51 (quoting Compl. ¶ 48) (emphasis added by the district court). From this statement the district court concluded that JSP "does not 'allege some harm arising from [the disclosure] that was separate from [the deadline extensions],' and thus any harm from the disclosure is not 'sufficiently separable' from the deadline extensions to support suit under FTCA." *Id.* at 51-52 (alterations in original) (quoting *Sloan*, 236 F.3d at 762). Similarly, FDA contends that JSP's challenges to the disclosure of its trade secrets "are intertwined with its broader challenge to the extension of the agency's deadlines." Br. of Appellee at 14. FDA observes that it examined the NDAs filed by JSP's competitors and found that "none of them used or relied upon [JSP's] information in any way." *Id.* However, this observation is irrelevant, for the only question at the pleading stage is whether JSP sufficiently alleged an injury caused by FDA's disclosure of its trade secrets. JSP's complaint specifically alleged that JSP suffered "substantial and irreparable injury" arising from FDA's disclosure of its trade secrets and confidential information, Compl. ¶¶ 75, 85, and sought more than $1.3 billion "for [JSP's] injuries resulting from [FDA's] misappropriation of [JSP's] trade secrets and breach of

FDA's confidential relationship with [JSP]," *id.* ¶ 118. Indeed, the complaint sought only declaratory relief, not damages, for JSP's injuries resulting from FDA's extensions of the NDA deadlines.

In construing JSP's tort claims as arising from FDA's deadline extensions, the district court cited two cases — *Sloan v. U.S. Department of Housing & Urban Development*, 236 F.3d 756, 762 (D.C. Cir. 2001), and *Fisher Bros. Sales, Inc. v. United States*, 46 F.3d 279, 286 (3d Cir. 1995) (en banc). *See JSP*, 319 F. Supp. 2d at 51. In *Sloan*, a contractor sued the Department of Housing and Urban Development under the FTCA for negligently conducting an audit of his construction site and for suspending him from government contract work based on the erroneous audit. 236 F.3d at 758-59. On appeal from the district court's dismissal of the complaint for lack of subject matter jurisdiction, the contractor contended that while the suspension of his government contract work was a discretionary function, the audit was not a discretionary function because it was governed by standards of professional practice. *Id.* at 761. The court rejected that contention, holding that there was "no meaningful way in which the allegedly negligent investigatory acts could be considered apart from the totality of the prosecution." *Id.* (quoting *Gray v. Bell*, 712 F.2d 490, 516 (D.C. Cir. 1983)) (internal quotation marks omitted). The court noted that "[t]he complaint does not allege any damages arising from the investigation itself, but only harm caused by the suspension to which it assertedly led." *Id.* at 762.

Similarly, in *Fisher*, Chilean fruit growers sued FDA under the FTCA for banning the importation of Chilean fruit based on a negligently conducted laboratory test concluding that the fruit contained cyanide. 46 F.3d at 282-83. Recognizing that the Commissioner's decision to ban the fruit was a discretionary function, the fruit growers alleged injury "based upon" the

negligence of the laboratory technicians, who were bound by FDA's Regulatory Procedures Manual. *Id.* at 286. The Third Circuit rejected this characterization of the claim, reasoning that "[t]he reality here is that the injuries of which the plaintiffs complain were caused by the Commissioner's decisions and, as a matter of law, their claims are therefore 'based upon' those decisions." *Id*. The court concluded that "a claim must be 'based upon' the exercise of a discretionary function whenever the *immediate cause* of the plaintiff's injury is a decision which is susceptible of policy analysis and which is made by an official legally authorized to make it." *Id.* at 282 (emphasis added).

Here, unlike in *Sloan* and *Fisher*, the district court could not conclude properly as a matter of law that none of JSP's alleged injuries were caused independently and immediately by FDA's disclosure of JSP's trade secrets. Whereas the contractor in *Sloan* did not allege injuries caused by the negligent audit, and the negligent laboratory test in *Fisher* could not injure the fruit growers unless the Commissioner relied on the test to ban the fruit, JSP did allege injuries caused by the disclosure of its trade secrets, and such disclosure could injure JSP even if FDA had not extended the NDA deadlines. Thus, the district court erred in treating JSP's tort claims as "based upon" FDA's deadline extensions.

B.

The district court also recast Counts I and II as claims of interference with contract rights. *See JSP*, 319 F. Supp. 2d at 50, 52 n.9. In so doing, the district court relied on *Art Metal-U.S.A., Inc. v. United States*, 753 F.2d 1151 (D.C. Cir. 1985), which held that the intentional tort exception to the FTCA includes claims of interference with prospective economic advantage. *Id.* at 1155. In *Art Metal*, the court treated a claim of interference with prospective economic advantage as a claim of interference with contract rights, which is barred by the intentional tort exception,

because the duty underlying both claims is the same — namely, the duty not to interfere with the plaintiff's economic relationship with a third party, whether or not that relationship is secured by a contract. *Id.* at 1154. Here, the district court treated JSP's claims of misappropriation of trade secrets and breach of a confidential relationship as a claim of interference with contract rights, even though the duties underlying the claims are different. The duty underlying the first set of claims is the duty not to disclose trade secrets and confidential information contained in JSP's NDA, whereas the duty underlying the second claim is the duty not to interfere with JSP's economic relationship with a third party, namely its business partner Watson Laboratories. *See JSP*, 319 F.2d at 52 n.9. Thus, the district court erred in treating Counts I and II of JSP's complaint as claims of interference with contract rights and dismissing them as barred by the intentional tort exception.

While FDA points to portions of the complaint characterizing the disclosure of JSP's trade secrets as "deliberate," Br. of Appellee at 25 (citing Compl. ¶ 95), the complaint also alleges that FDA believed the disclosure to be an "accident," Compl. ¶ 46. But whether the disclosure was intentional or negligent does not determine whether the intentional tort exception applies, for the FTCA expressly states the claims that the exception bars, and it does not include misappropriation of trade secrets or breach of confidentiality. *See* 28 U.S.C. § 2680(h). The court's task is limited to identifying "'those circumstances which are within the words and reason of the exception' — no less and no more." *Kosak v. United States*, 465 U.S. 848, 853 n.9 (1984) (quoting *Dalehite v. United States*, 346 U.S. 15, 31 (1953)).

The Second Circuit's decision in *Kramer v. U.S. Department of the Army*, 653 F.2d 726 (2d Cir. 1980), supports JSP's claim of error. In that case, a manufacturer of mortar

projectiles sued the Army for wrongfully terminating her contract, disclosing confidential information about her exclusive supplier of forging blanks to a competing manufacturer, and then awarding the contract to the competing manufacturer. 653 F.2d at 728. While the pro se plaintiff labeled her claim as one of "conversion," the district court treated it as a claim of intentional interference with contract rights, which it dismissed as barred by the intentional tort exception to the FTCA. *Id.* at 729. The Second Circuit reversed, holding that the plaintiff's "putative 'conversion' claim must be viewed as a cause of action for misappropriation of a trade secret recognized under New York law and consequently within the district court's jurisdiction under the Federal Tort Claims Act." *Id.* The court explained that, "[s]tripped to their essentials, [the plaintiff's] factual allegations reduce to this: the Government induced [the plaintiff] to disclose the identity of her supplier in confidence, and then divulged that information to others in breach of that confidence." *Id.* The court concluded that the complaint stated a claim for misappropriation of trade secrets, not a claim for interference with contract rights. *Id.*

Counts I and II of JSP's complaint, "stripped to their essentials," reduce to this: FDA induced JSP to disclose its trade secrets in confidence, and then it divulged that information to others in breach of that confidence. Thus, JSP's complaint sufficiently alleges claims for misappropriation of trade secrets and breach of a confidential relationship. FDA's only response is that "whether the plaintiff's claims were potentially barred as arising out of 'interference with contract rights' . . . was neither raised nor addressed in *Kramer*." Br. of Appellee at 28. FDA is mistaken, however, because the Second Circuit reversed the district court's dismissal of the complaint on this very basis. Counts I and II therefore must be reinstated.

III.

Under the APA, a reviewing court must set aside an agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). A court may not review an agency action, however, if the "agency action is committed to agency discretion by law." *Id*. § 701(a)(2). In *Heckler v*. *Chaney*, 470 U.S. 821 (1985), the Supreme Court held that "an agency's decision not to prosecute or enforce, whether through civil or criminal process, is a decision generally committed to an agency's absolute discretion" and therefore is presumptively unreviewable. *Id*. at 831. This presumption of unreviewability may be overcome "where the substantive statute has provided guidelines for the agency to follow in exercising its enforcement powers," or "where the agency has conspicuously and expressly adopted a general policy that is so extreme as to amount to an abdication of its statutory responsibilities." *Baltimore Gas & Elec. Co. v. FERC*, 252 F.3d 456, 460 (D.C. Cir. 2001) (quoting *Chaney*, 470 U.S. at 833 & n.4) (internal quotation marks omitted).

In dismissing Count VI of JSP's complaint, the district court ruled that FDA's extensions of the NDA deadlines "qualify as decisions not to prosecute or enforce, and therefore enjoy a presumption of unreviewability." *JSP*, 319 F. Supp. 2d at 56. It explained that FDA had announced in its August 14, 1997 notice that unapproved LS drugs would "be subject to regulatory action" after August 14, 2000, *id.* (quoting 62 Fed. Reg. at 43,538), and that FDA's subsequent deadline extensions constituted exercises of its enforcement discretion based on "a balancing of factors that clearly fall within FDA's expertise, such as the medical necessity of LS drugs and the period of time needed to transition millions of patients safely from an unapproved- to an approved-drug system," *id.*; *see* 65 Fed. Reg. at 24,489; 66 Fed. Reg. at 36,794. The district court then examined 21 U.S.C. § 355 and 21 U.S.C. § 393, which JSP claimed to provide guidance for FDA's exercise of enforcement

discretion, and concluded that neither provision "provides enforcement guidelines sufficient to overcome the presumption of unreviewability." *JSP*, 319 F. Supp. 2d at 56 (citing *Chaney*, 470 U.S. at 832-33). The district court noted that the Supreme Court held in *Chaney* that 21 U.S.C. § 355, which prohibits the introduction of unapproved new drugs into the market and describes the NDA approval process, is "simply irrelevant to the agency's discretion to refuse to initiate [enforcement] proceedings." *Id.* (alteration in original) (quoting *Chaney*, 470 U.S. at 836) (internal quotation marks omitted). The district court also concluded that 21 U.S.C. § 393, which sets forth FDA's mission statement, "does not address enforcement . . . and if anything only underscores FDA's authority to determine how best to ensure the safety and effectiveness of drugs." *Id.* at 56-57 (citing *Safe Energy Coalition v. Nuclear Regulatory Comm'n*, 866 F.2d 1473, 1478 (D.C. Cir. 1989)). Finally, the district court ruled that FDA's deadline extensions did not amount to "an abdication of its statutory responsibilities" because the extensions did not "constitute a permanent policy for all existing new drug products . . . but rather were limited to non-approved manufacturers for a period of three years." *Id.* at 57 (citing *Shell Oil Co. v. EPA*, 950 F.2d 741, 765 (D.C. Cir. 1991)).

JSP does not dispute any of the district court's legal conclusions. Rather, it contends that the district court focused "too narrowly" on its challenge to FDA's deadline extensions and ignored its broader challenge to "FDA's entire course of conduct in the LS drug program going back to the August 1997 Notice." Br. of Appellant at 37. Count VI of the complaint alleged that FDA "acted arbitrarily, capriciously, and in violation of 21 U.S.C. §§ 355; 393" when it (1) extended its August 14, 2000 approval deadline to August 14, 2001, Compl. ¶ 112; (2) changed its August 14, 2001 approval deadline to a filing deadline and allowed manufacturers with pending NDAs to continue marketing unapproved LS drugs until August 14, 2003,

Compl. ¶ 113; (3) "departed from consistent and longstanding precedent" by allowing manufacturers to continue marketing unapproved LS drugs for three years after Unithroid's approval, Compl. ¶ 115; and (4) took "inconsistent positions" by finding unapproved LS drugs to be unstable and unsafe and yet permitting unapproved LS drugs to be marketed for three years after Unithroid's approval, Compl. ¶ 117. These allegations essentially challenge three FDA actions: (1) extension of the August 14, 2000 deadline to August 14, 2001; (2) conversion of the August 14, 2001 approval deadline into a filing deadline; and (3) authorization of manufacturers with pending NDAs to continue marketing unapproved LS drugs until August 14, 2003. Each of these actions is an exercise of FDA's enforcement discretion, and JSP fails to demonstrate how 21 U.S.C. § 355 and 21 U.S.C. § 393 provide guidelines for the exercise of such discretion. To the extent JSP also contends that the district court should have allowed it to amend its complaint, JSP did not seek to amend its complaint and thus cannot show error by the district court for failing to afford unrequested relief. *See United States ex rel. Totten v. Bombardier Corp.*, 286 F.3d 542, 552-53 (D.C. Cir. 2002).

Accordingly, we affirm the dismissal of Count VI, reverse the dismissal of Counts I and II of JSP's complaint, and remand the case to the district court for further proceedings.